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Document Processing Center EPA East (Mail Code 7407M) Attn: TSCA Section 8(e) U.S. Environmental Protection Agency 1201 Constitution Avenue, NW Washington DC 20460-0001



**Subject:** Notice in accordance with Section 8(e): Results of a Full-Scale Prenatal Developmental Toxicity in Sprague Dawley Rats with 2-Ethylhexanal

(CAS# 123-05-07)

Ladies and Gentlemen:

BASF Corporation is submitting results of a prenatal developmental toxicity study in Sprague Dawley rats with 2-Ethylhexanal (CAS# 123-05-07) conducted for BG Chemie, PO Box 101480, 69004 Heidelberg, Germany by Huntingdon Life Sciences Ltd., Eye, Suffolk, IP23 7PX, England.

The study was carried out in accordance with or exceeding the requirements of the following guideline:

OECD Guidelines for Testing of Chemicals, Test Guideline 414 (2<sup>nd</sup> draft), Prenatal Developmental Toxicity (Oct. 1998)

The test substance was administered orally by gavage to 25 pregnant female Sprague rats/group at doses of 0; 100; 300 and 800 mg/kg body weight/day on day 6 through day 19 post coitum (p.c.).

## The following is a summary of the most relevant results:

Maternal toxicity occurred exclusively at high dose level (800 mg/kg).

Most salient findings were significantly reduced food consumption (by 14%), and decreased absolute (23% below control) and corrected (39% below control) body weight gain. At initiation of treatment (gestation days 6-7) even a body weight loss was noted.

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Moreover, the high dose females showed adverse clinical findings like piloerection, underactivity, hunched posture and partly closed eyelids.

Signs of developmental toxicity occurred at 300 and 800 mg/kg body weight/day, but not at the low dose level.

At 800 mg/kg fetal and placental weights were significantly low and a large number of visceral and skeletal findings were observed (e.g. dilated brain ventricles, absent/rudimentary thyroid, cardiovascular abnormalities, rudimentary/absent renal papillae, a high number of rib and vertebral configuration abnormalities, and general reductions in the degree of ossification).

At 300 mg/kg there was some evidence of a slight retardation in fetal development as indicated by marginally lower fetal body weights and some delays in skeletal maturation.

BASF Corporation understands that reporting of the results from this study under TSCA 8(e) is in accordance with EPA's policy. The MSDS will be updated with this new information.

Please send all correspondence related to the TSCA 8 (e) submissions to the Wyandotte, MI address listed below.

If you have any questions please call Dr. Sree Jasti at 734-324-5107. Thank you for your consideration.

Śincerely,

Sree L. Jasti, Ph.D.

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**Product Regulatory Center of Excellence** 

BASF Corporation

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Enc.

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